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Patent and Trademark Office**

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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/403,437 12/20/99 ODIDI

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EXAMINER

PULLIAM, A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1615

8

DATE MAILED: 12/19/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/403,437

Applicant(s)

ODIDI ET AL.

Examiner

Amy E Pulliam

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 20 December 1999.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

## DETAILED ACTION

Receipt is acknowledged of the Small Entity Claim, The Declaration, the Information Disclosure Statement, and the Preliminary Amendment A, received October 21, 1999, December 20, 1999, January 18, 2000, and December 20, 1999, respectively.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 6, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 3,870,790 to Lowey *et al.*. Lowey *et al.* teach a solid pharmaceutical composition in which the core comprises a pharmaceutical active, and a carrier made of hydroxypropylmethyl cellulose admixed with ethylcellulose (abstract). Lowey *et al.* teach that the formulation will release the active over a prolonged period of time. Lowey *et al.* also allow for the inclusion of various excipients. Lastly, Lowey *et al.* teach that their invention can be used with any active ingredient. They state, "the nature of the therapeutic agent is not critical and any drug, or stable combination of drugs, can be incorporated into these novel pharmaceutical forms." (see c 5, l 59-62) Therefore, this general disclosure anticipates the above listed claims.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lowey *et al.*, as discussed above, in view of US 5,162,117 to Stupak *et al.*. Lowey *et al.* is discussed above as disclosing a pharmaceutical composition comprising a carrier made of hydroxypropylmethyl cellulose and ethyl cellulose, as well as a pharmaceutical active, and excipients. Lowey *et al.* does not teach the specific additives and excipient as claimed by applicant.

Stupak *et al.* is relied upon for the teaching that applicant's claimed excipients are all very well known in the pharmaceutical art, and therefore would have been obvious to include in any pharmaceutical formulation, especially one which has the same function of controlled release. Stupak *et al.* disclose a controlled release solid dosage tablet. More specifically, Stupak *et al.* teach that the tablet core of their invention can include excipients including diluents such as microcrystalline cellulose, lubricants, glidants such as silicon dioxide, as well as sodium lauryl sulfate and lactose (c 2-3). Additionally, Stupak *et al.* teach that their composition can have a coating, which can be a methacrylic acid copolymer coating (c 5, claim 5). Again, the Stupak reference is relied upon to show that applicant's claimed excipients are all known in the

art of pharmaceutical formulations, and therefore would be obvious to include in a tablet formulation.

It is the position of the examiner that the main component of applicant's invention is the mixture of polymers in the core of the composition, which is disclosed generally by Lowey *et al.*. Lowey *et al.* does not teach that the hydrophilic polymer be a mixture of hydroxypropylmethylcellulose and hydroxyethylcellulose. However, it is the position of the examiner that because these two polymers act so similarly, and are often interchangeable in a pharmaceutical composition, it would have been obvious to one of ordinary skill in the art to use one or the other or a mixture of the two hydrophilic polymers. As stated in *In Re Kerkhoven*, 205 USPQ 1069, 1072 (CCPA- 1980), "It is prima facie obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. As this court explained in *Crockett*, 126 USPQ 186, 188 (CCPA- 1960), the idea of combining them flows logically from their having been individually taught in the prior art. Therefore, because Lowey *et al.* teach the mixing of HPMC with ethylcellulose, it is the position of the examiner that Lowey *et al.*'s disclosure in view of Stupak's disclosure suggests applicant's claimed invention. Further, one of ordinary skill in the art would have been motivated to combine the teachings of Lowey *et al.* and Stupak *et al.*, and use any of the well known pharmaceutical excipients in the composition disclosed by Lowey *et al.*. The expected result would be a successful controlled release pharmaceutical composition. Therefore, this invention as a whole

would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is (703) 308-4710. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7922 for regular communications and (703) 308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Amy E. Pulliam  
Patent Examiner  
Art Unit 1615  
December 15, 2000

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
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